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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

BROOKLYN OFFICE

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UNITED STATES OF AMERICA
ex rel. DON HANKS, *et al.*,

Plaintiffs,

No. 08-CV-3096 (SJ)(RML)

v.

MEMORANDUM
AND ORDER

U.S. ONCOLOGY SPECIALITY, LLP, *et al.*,

Defendants.
-----X

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JOHNSON, Senior District Judge:

Relator Don Hanks, who worked for Amgen, Inc., as a nephrology and/or oncology sales representative for approximately 17½ years prior to his termination on May 23, 2007, brings this *qui tam* action on behalf the United States and 13 states, alleging that 18 Group Purchasing Organizations (“GPOs”) or medical practices (collectively, “Defendants”) violated the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and similar state laws by submitting claims to Medicare, Medicaid and other Government Healthcare Programs for reimbursement for Amgen drugs without reporting that they had accepted discounts, rebates and/or other financial incentives from Amgen in violation of the Anti-kickback Statute, 42 U.S.C. § 1320a-7b. All but one of the Defendants—along with 21st Century Oncology of

Jacksonville LLC (“21st Century”), which has never been named as a defendant in this action—now move to dismiss the Fifth Amended Complaint (the “FAC”) on various grounds, arguing, *inter alia*, that the “public disclosure bar” and “first-to-file rule” apply to this case and that the FAC fails to allege any of the causes of action with sufficient particularity. For the reasons set forth below, Defendants’ motions are granted in part and denied in part and this action is dismissed without prejudice.

BACKGROUND

This is one of at least 11 federal *qui tam* actions that have been filed nationwide relating to sales practices used by Amgen, Inc., a biotechnology and drug manufacturing company, in marketing Aranesp, a drug which stimulates the production of red blood cells. Except as otherwise indicated, the following facts are drawn from the FAC (Dkt. No. 51) and are assumed to be true for purposes of deciding the instant motions to dismiss (the “Motions”).

The Amgen Drugs at Issue

In the 1980s and 1990s, Amgen developed two types of erythropoiesis-stimulating agents or “ESAs”—drugs that stimulate the body’s production of red blood cells. The first of these, epoetin alfa, was approved by the U.S. Food and Drug Administration (the “FDA”) in 1989 for the treatment for anemia associated

with chronic renal failure (“CRF”) (66).¹ Thereafter, Amgen marketed the drug under the brand name “Epogen.” (68).

In 1985, while epoetin alfa was still in development, Amgen entered into a product licensing agreement which gave the licensee the exclusive right to market the drug for all “indications” other than the treatment of anemia associated with CRF in dialysis patients. (67). In the 1990s, the licensee obtained FDA approval to market the drugs for treatment of anemia in cancer patients undergoing chemotherapy, HIV patients taking the antiretroviral medication Zidovudine, pre-dialysis patients suffering from kidney disease and anemic patients scheduled to undergo elective, non-cardiac, non-vascular surgery. (69). The licensee marketed its product—which was identical to Epogen—under the brand name Procrit. (68).

In 1997, a joint venture owned in part by Amgen produced yet another ESA—darbepoetin alfa—which had a slightly different molecular structure than the first ESA. (71). In September 2001, after fending off a legal challenge from the licensee, Amgen obtained FDA approval to market darbepoetin alfa for use in chemotherapy-induced anemia. (73). Thereafter, Amgen began marketing the drug in the United States under the brand name Aranesp. (73).

¹ Numbers in parentheses denote paragraphs in the FAC.

Amgen's Marketing Techniques

Overfill, Free Samples, Off-label Uses and Honoraria

Amgen used a variety of methods to promote Aranesp and to compete with Procrit. Beginning in 2001, Amgen used “overfill”—the practice of filling a vial with more product than was reported on the invoice—to provide customers with free products. (185). Amgen also gave each sales representative \$50,000 in free samples and encouraged them to distribute them liberally. (195).

Amgen conducted seminars for doctors, their families and their employees at which meals were served free of charge. For example, doctors and their families were invited to dinners billed as “roundtable discussions,” even though “it was often the case that no medical discussions took place” at those events. (2d 207).² Doctors were also paid honoraria of \$1,000 just for attending. (2d 207). Similarly, the employees of medical practices were invited to “reimbursement roundtables” at which they received meals but no billing advice. (208).

Amgen also touted Aranesp's “off-label” uses—that is, uses other than the FDA-approved use: the treatment of chemotherapy-induced anemia. (211). Amgen provided oncology sales representatives with a “proof source book,” which included materials that would enable the salesforce to market Aranesp for a “range of different uses.” (211). Although the book contained numerous warnings stating that it was for “information purposes only,” the book enabled sales representatives

² The FAC contains two paragraphs numbered 207.

to market the drug for uses, like the treatment of anemia in Zidovudine-treated HIV patients, for which only Procrit had been FDA-approved. (211).

“Marketing the Spread” and “Tying Arrangements”

Amgen also competed with Procrit by offering rebates and/or discounts to reduce the cost of Aranesp to medical providers, while failing to report these rebates and discounts in order to maximize the average wholesale price, the average sales price and other benchmarks used by the Government to calculate the reimbursement providers receive for administering the drug. The salesforce would then market the “spread” between the cost of, and Government reimbursement for, the drugs. (198). To facilitate this, Amgen provided Relator with a “calculation tool” that enabled him to estimate the profits a customer could realize from the spread, which the salesforce called “over-reimbursement.” (197-98).

The size of the rebates, discounts, and other monetary incentives available depended in large part on the amount of Amgen drugs that a customer purchased. (78). The amount was based on the purchases of all Amgen products, including Neupogen and Neulasta—granulocyte colony-stimulating agents, or “GSAs,” which stimulate the production of a type of white blood cell. (180). At least initially, Amgen alone produced these GSAs. Since medical providers had no choice but to purchase the GSAs from Amgen, this “tying arrangement” gave the providers a financial incentive to prefer Aranesp to Procrit.

Not all customers were offered the same schedule of rebates, discounts and financial incentives. The schedules varied depending on the customer's potential to make annual purchases of Aranesp, Neupogen and Neulasta (collectively, the "Covered Drugs"). (83). Those customers considered capable of annual purchases of up to \$700,000 were placed the "Silver" category, those considered capable of annual purchases between \$700,000 and \$5 million were "Gold" customers, and those considered capable of annual purchases of more than \$5 million were "Platinum" customers. (83). According to the FAC, a typical Gold customer received rebates, discounts and incentives totaling at least 40% of the invoiced charge for Covered Drugs, with many Gold customers receiving a reduction in the range of 50%. (26). Typical Platinum customers received at least 50%, and many received in the range of 60%. (26).

With each new contract, Amgen ratcheted up the level of purchases needed to retain a given level of financial benefits. (90). Thus, a customer would have to purchase more and more to receive the same level of rebates, discounts and other financial incentives from Amgen. Relator reasons that unless a customer's patient base increased in proportion to the increase in purchases required, this structure would give the customer a financial incentive to overprescribe the drugs by either prescribing more than a patient needed or prescribing drugs which were not medically necessary.

Manipulation of the Average Wholesale Price and Average Sales Price

In order to increase the amount of reimbursement its customers would receive, Amgen manipulated the Average Wholesale Price and Average Sales Price. Prior to 2005, the Average Wholesale Price (“AWP”) was used by the Centers for Medicare and Medicaid (“CMS”), an agency of the U.S. Department of Health and Human Services (“HHS”), to determine the levels of reimbursement medical providers would receive for administering Aranesp and other drugs to Medicare and Medicaid recipients. (8, 120). Since January 1, 2005, the reimbursement rates for the Covered Drugs and other “biologicals” have been calculated by taking the Average Sales Price (“ASP”) and adding a 6% markup. (5, 121, 124).

ASP is calculated quarterly by totaling a manufacturer’s quarterly sales to all purchasers in the United States for a particular drug, then dividing that sum by the number of units of that drug sold in that quarter. (121-22). Manufacturers are supposed to deduct price concessions offered on a “lagged basis”—that is, not given at the time of sale—in calculating total sales. (121). From April 30, 2004, until September 30, 2011, Amgen failed to properly account for price concessions including rebates, volume discounts and overfill, and knowingly reported an inaccurate ASP for Aranesp, Epogen, Neupogen and Neulasta. (126). Defendants, who were buyers of these drugs during the aforementioned period, knowingly

benefitted from this practice by receiving reimbursement from the Government that exceeded their costs. (77, 127).

Procedural History of this Action

On January 24, 2008, Relator commenced this *qui tam* action on behalf of the United States, alleging that Amgen and three medical providers—Florida Cancer Specialists (“FCS”), Gulfcoast Oncology Associates (“GOA”), and Integrated Community Oncology Network, LLC (“ICON”)—violated the federal False Claims Act. In its 14-page “Complaint under the Qui Tam Provisions of the False Claims Act,” which was initially filed in the United States District Court for the Middle District of Florida, Relator principally alleged that Amgen had defrauded government healthcare programs by “falsely representing the prices of its drugs, engaging in improper sales and marketing schemes such as promoting off-label sales and ‘marketing the spread,’ and paying illegal kickbacks to physicians.” (Original Complaint (Dkt. No. 10), ¶ 2). That pleading also accused FCS, GOA and ICON of receiving kickbacks and submitting false and fraudulent claims for reimbursement to government healthcare programs, alleging that the three medical practices each received several million dollars a year in rebates from Amgen, filed claims for Medicare and Medicaid reimbursement for “overfill” they received for free, and accepted sham honoraria. (*Id.*, ¶¶ 28-32).

In July 2008, the United States moved pursuant to 28 U.S.C. §1404(a) to transfer this action to this district. The Government noted that there were already

four previously filed *qui tam* actions pending against Amgen in the Eastern District of New York. The motion, which was filed *ex parte* because the motion papers disclosed the names of the other relators, was granted on July 28, 2008.

On November 30, 2011, Relator filed a First Amended Complaint which exceeded 100 pages in length. That pleading still named Amgen, FCS, GOA and ICON as defendants, but added approximately 200 others: a GPO named U.S. Oncology Specialty, LP (“USOS”) and 195 medical providers from 40 different states. Relator sued the 79 defendants which were located in states with laws analogous to the FCA on behalf of those states, as well as on behalf of the United States.

Approximately one month later, Relator amended his pleading to name 102 new medical practices. The Second Amended Complaint exceeded 180 pages in length (including the caption and a six-page Table of Contents) and named over 300 defendants from 43 states and the District of Columbia. It contained 23 causes of action, including one alleging violations of the FCA by Amgen, one alleging violations of the FCA by the Medical Providers, and one alleging FCA retaliation by Amgen against Relator. The remaining 20 counts alleged violations of the laws of 19 states and the District of Columbia (collectively, “the States”).

In December 2012, the United States intervened with respect to certain claims against Amgen after the United States, Amgen, Relator and the relators in other, similar actions reached a settlement of those claims. (Dkt. No. 32, Ex. A).

The settlement agreement provided, *inter alia*, that upon Amgen's payment of sums specified in paragraph 1 of the agreement, the parties would stipulate to dismiss the claims against Amgen. (*Id.*, ¶ 17). That "Stipulation of Dismissal and Order of Claims against Amgen, Inc." was ultimately submitted on October 31, 2013, (Dkt. No. 46), and "so ordered" on November 20, 2013. (Dkt. No. 47).

The States declined to intervene in this action. However, in a document entitled States' Notice of Declination to Intervene, the States noted that they had reached an agreement with Relator and Amgen in April 2013, which resolved the claims that Relator had brought against Amgen on the States' behalf. (Dkt. No. 40). As a result, the Third Amended Complaint, which was filed on May 3, 2013, contained only one claim against Amgen: Relator's FCA retaliation claim pursuant to 31 U.S.C. § 3730(h). Amgen, Relator and Amgen subsequently stipulated to dismiss that claim with prejudice, (Document Nos. 52, 71), eliminating the last remaining cause of action against Amgen.

On April 29, 2014, Relator moved pursuant to Fed. R. Civ. P. 15(a) for permission to amend his pleading for a fourth time. In a Memorandum of Points and Authorities in Support of Plaintiff/Relator's Motion for Leave to Amend (Dkt. No. 48-1), Relator explained that he wished to add "an entirely new allegation of a 'hub and spokes' conspiracy involving numerous Oncology Practices that ... [allegedly] committed fraud against the Centers for Medicare and Medicaid Reimbursement," and to "substantially limit[] the number of named defendants

compared to the previous complaint.” (*Id.*, p. 2). Relator’s memorandum did not explain why Relator proposed dismissing all but 18 of the over 300 defendants or why Relator named the proposed pleading the Fifth Amended Complaint, rather than the Fourth Amended Complaint.

None of the Defendants filed a written objection to Relator’s motion. At a status conference on May 9, 2014, the Court granted Relator permission to file his proposed Fifth Amended Complaint and directed Relator to serve the amended pleading on the 18 named defendants. Relator filed the Fifth Amended Complaint on May 30, 2014.

The Fifth Amended Complaint

The Defendants

The 18 defendants named in the FAC can be grouped into three categories. In the first category is U.S. Oncology Specialty, LP (“USOS”), a “specialty distribution center service of U.S. Oncology, Inc.” (27). USOS is a GPO which served as the buying agent for approximately 1,000 medical practices located in at least 11 states having laws analogous to the FCA: California, Illinois, Indiana, Louisiana, Massachusetts, Michigan, New Jersey, New York, Oklahoma, Texas and Virginia. (29). Relator sues USOS on behalf of the United States and these 11 states.

In the second category are a dozen oncology practices located in the State of Florida (collectively, the “Florida Defendants”). Two of the 12—FCS and ICON—

are large practices, operating 46 and 9 offices, respectively. (35, 37). Another, GOA is alleged to be an affiliate of ICON. (36). The remaining nine practices—Hematology and Oncology Associates of the Treasure Coast (“Treasure Coast”), Mid-Florida Hematology and Oncology Centers, P.A. (“Mid-Florida”), Pasco Hernando Oncology Associates, P.A. (“Pasco Hernando”), Regional Consultants in Hematology and Oncology (“Regional”), Cancer Institute of Florida, P.A. (“CIF”), Coastal Oncology, PL (“Coastal”), Stuart Oncology Associates, P.A. (“Stuart”); Ayub, Sokoi, Matzkowitz and Sennabaum, d/b/a New Hope Cancer Center (“New Hope”) and David Dresdner, M.D. (“Dresdner”)—are each alleged to operate a single office in Florida. (39-57). Relator sues the Florida Defendants on behalf of both the United States and the State of Florida.

In the third category are five oncology practices located in the State of Georgia (collectively, the “Georgia Defendants”). These five practices—Georgia Cancer Specialists Administrative Annex (“GCS”), Northwest Georgia Oncology Centers, P.C. (“Northwest Georgia”), Augusta Oncology Associates (“Augusta”), Central Georgia Cancer Care (“Central Georgia”), and Southeast Georgia Hematology/Oncology Associates, P.C. (“Southeast Georgia”)—are each alleged to operate a single office in Georgia. (58-62). Relator sues the Georgia Defendants on behalf of both the United States and the State of Georgia.

The Allegations relating to USOS

The FAC alleges that Relator met with the President of USOC on “multiple occasions” regarding the sale of the Covered Drugs, including at the 2003, 2005, and 2006 annual meetings of the American Society of Hematology. (33). Relator also met with other representatives of USOS at those meetings and at the 2005 annual meeting of the American Society of Community Oncologists. (33). Relator implies that, during these interactions, he or other Amgen representatives “marketed the spread,” making USOS “aware ... of the opportunity to obtain greater reimbursement for the Covered Drugs than USOS was lawfully entitled to receive from Government Healthcare Programs.” (33). Indeed, because “the USOS GPO pooled the purchasing power of its member physicians and oncology practices,” it was able “to obtain even larger rebates for the Covered Drugs ... than Amgen offered to smaller practices,” (29), and “rebates and other discounts ... far greater than those generally available to other ... GPOs.” (32). USOS representatives, including its President, “made clear to Relator that Aranesp would be the ... ESA ... of choice for USOS based on the ‘profit per patient’ that USOS could achieve by using Aranesp, especially in combination with Neupogen and Neulasta.” (33).

According to the FAC, USOS thereafter sought Government reimbursement for Covered Drugs “that overstated its actual cost of the Covered Drugs.” (33). Since USOS did not disclose to the Government that the price it paid to Amgen was

“considerably lower than the reported selling price,” and that its confidential contracts with Amgen provided for other forms of discounts, the Government reimbursed the GPO “more than it was entitled to receive.” (29-30). The FAC alleges that USOS admitted as much in a press release, stating that it had “sought and been reimbursed by Government Healthcare Programs on the basis of the unadjusted ‘average selling price’ of the drugs, as computed by Amgen, a figure which did not factor in the discounts, rebates, and other cost-reducing elements received by the GPO.” (31).

The Allegations relating to the other 17 Defendants

FCS, GOA and ICON were “elite members of the International Oncology Network ... and received even greater discounts on drug[s] purchased from Amgen because of this affiliation.” (38). In addition, ICON “had a GPO contract and a special Large Physician Practice ... contract with Amgen.” (37). The FAC does not allege what additional benefits ICON received as a result of these contracts.

The FAC does allege, based on information and belief, the dollar amount of Amgen products that GOA and ICON purchased in each calendar year from 2002 to 2007, and the dollar amount of Amgen products that FCS purchased in each calendar year from 2004 to 2007. The FAC further alleges that all of these defendants, as “Platinum” customers, received “a rebate or discount from Amgen amounting to approximately 50% of all purchases made ... during the period of approximately 2004 through 2007.” (35-37). Relator, who was terminated by

Amgen in May 2007, has no sales figures for years after 2007, but speculates, upon information and belief, that these defendants “made comparable purchases of Amgen drugs and received comparable rebates” on those purchases for the period from September 1, 2001, to at least September 30, 2011 (the “Covered Period”). (35-37).

The FAC alleges very little about the remaining 14 defendants. The FAC alleges that each of these defendants was an Amgen customer assigned a number in the “Amgen Customer Identification System” or “ACIS,” a computer database used by Amgen to track the rebates, discounts, free goods, honoraria, data purchases and other gifts and grants given to each customer. (34). The pleading alleges, on information and belief, the dollar amount of drugs purchased by each defendant during the Fourth Quarter of 2006. (39-62). The FAC then alleges, on information and belief, whether the defendant is a Platinum or Gold customer, and what rebate such a customer would receive: “approximately 50%” in the case of Platinum customers and “approximately 40%” in the case of Gold customers. (39-62). Finally, the FAC alleges—again on information and belief—that these defendants “made comparable purchases of Amgen drugs and received comparable rebates” on those purchases during the entire Covered Period. (39-62).

The Federal Cause of Action

The FAC alleges 14 causes of action: one claim pursuant to the FCA and 13 counts alleging violations of analogous State laws. Count One, the FCA claim,

alleges that the Defendants “engaged in fraudulent activities including but not limited to” the following: 1) “purchasing the Covered Drugs and submitting claims to Government Healthcare Programs for ... reimbursement for those drugs in order to receive rebates, discounts and other financial incentives ... from Amgen;” 2) submitting claims to Government Healthcare Programs for reimbursement for the Covered Drugs which “failed to account for the rebates, discounts, drug ‘overfills,’ kickbacks and other financial incentives received from Amgen;” and 3) seeking Government reimbursement for Covered Drugs that “were administered to patients when not medically necessary or, while medically necessary, were administered in an amount greater than medically necessary for the patient or in an amount greater than necessary to obtain the medical benefit for the patient.” (2d 232). Relator alleges that these “fraudulent activities” violated 31 U.S.C. §§ 3729(a)(1), (a)(2) and (a)(3). (2d 233).

Although the title of Count One states that it is alleging violations of the FCA by “Defendant Oncology Practices as Specified Herein,” the Count itself contains no allegations regarding specific defendants. It also does not allege 1) when the false or fraudulent claims were filed, 2) the Government entity with which the claims were filed, 3) or why the claims were false or fraudulent. Rather, the Count merely “incorporates by reference the allegations of paragraphs 1-229” of the FAC, (253), leaving it to the Defendants to guess, at their peril, the theories of liability on which Count One relies.

To be sure, there are some clues regarding Relator's theory elsewhere in the FAC. The FAC specifically alleges that "FCA liability may be premised on a violation of the Anti-kickback Statute," (140), since compliance with the Anti-kickback Statute is "a precondition to participation as a health care provider under a Government Health Care Program," and "a *condition of payment* for drug claims administered by physicians for which Medicare or Medicaid reimbursement is sought." (136) (emphasis in original). The FAC does not allege that the claims filed by Defendants for reimbursement from the Government for Covered Drugs expressly certified compliance with the Anti-kickback Statute. Rather, paragraph 152(b), which alleges that the Defendants' claims for reimbursement were "false ... by omission," suggests an implied false certification theory: that Defendants, through their participation in the federally funded programs, impliedly certified their compliance with the statute.

Paragraph 152(c) charges that each of Defendants' claims for reimbursement violated the Anti-kickback Statute, which "prohibits any person or entity from knowingly and willfully offering to pay or paying any remuneration to another person to induce that person to purchase, order, or recommend any good or item for which payment may be made in whole or in part by a federal health care program, which includes an State health program or health program funded in part by the federal government." (132). The FAC acknowledges that rebates and discounts which fit within "safe harbors" set forth in 42 C.F.R. § 1001.952 do not

violate the Anti-kickback Statute. (134). However, the pleading specifically alleges that the rebates, discounts and other incentives offered by Amgen did not fit within a safe harbor. (141). Citing to a document authored by the Office of the Inspector General of HHS (the “OIG”), which Relator later characterizes as the “OIG’s Commentary on the Final Rule,” (142), Relator alleges:

Generally speaking, discounts for health care items and services are encouraged under Government Healthcare Program rules. Federal healthcare program regulations specifically approve of discounts, so long as the programs themselves share in the discount where appropriate, and as appropriate, to the reimbursement methodology. But arrangements in which federal healthcare programs get less than their proportional share of cost-savings on items or services payable by the programs are deemed “seriously abusive.” Such arrangements result in overcharges to the programs and are not protected by either the statutory exception or regulatory safe harbor for some types of discounts. (133) (citing 64 Fed. Reg. 63526).

The FAC also quotes that portion of the document which stated:

A rebate under our proposal would be defined as any discount not given at the time of sale. Consequently, a rebate transaction would not be covered by the safe harbor if it involves a buyer that is neither a cost reporter nor a [health maintenance organization] or [competitive medical plan] because for such buyers, all discounts must be given at the time of sale. (142).

The pleading specifically alleges that “[n]one of defendant Oncology Practices qualified as a ‘cost reporter,’ an ‘HMO’ or a ‘CMP’ under the Final Rule.” (143).

In addition, the FAC alleges that that “the rebates, discounts and other incentives

paid to the defendant Oncology Practices pursuant to the Amgen Portfolio Contract ... were not discounts given at the time of sale” (141).

The FAC suggests two other theories of liability in paragraph 152(a), which alleges that each defendant filed claims with government healthcare programs that were improper in one of two ways. First, the pleading alleges that each such claim was “false or fraudulent in that it failed to report or identify the post-sale rebates, discounts and other things of value earned by the defendant under an Amgen Portfolio Contract and paid to it by Amgen.” The pleading asserts that Defendants were required to report “any discount not given at the time of sale in accordance with 42 C.F.R. §1001.952(h)(1)(ii)(C),” but that “none of the Oncology Practices defendants ever reported these cost reductions to the Government Healthcare Programs.” (80).

Second, paragraph 152(a)(ii) alleges that each claim was improper because it sought reimbursement for drugs that “were known or should have been known to be not medically necessary, or not medically necessary at the dosage levels ... administered, both in violation of 42 U.S.C. § 1320a-7a.” The FAC alleges that 42 U.S.C.A. § 1395y(a)(1)(A) provides that no payment may be made under the Medicare statute for any expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury. (137). The pleading then quotes *Mikes v. Straus*, 274 F.3d 687, 701 (2d Cir. 2001), which held that “[s]ince § 1395y(a)(1)(A) expressly prohibits payment if a provider fails

to comply with its terms, defendants' submission of the claim forms implicitly certifies compliance with its provision." (138) (emphasis in *Mikes*).

The FAC does not allege facts to support this claim of unethical behavior on the part of 16 of the 18 Defendants. However, with respect to Southeast Georgia and ICON, the FAC alleges some circumstantial evidence of excessive use of Aranesp. According to the pleading, Relator overheard one of the doctors affiliated with Southeast Georgia say that he prescribed Aranesp and Neulasta for all of his patients, even though only some "actually need it." (173, 215). Either Relator or another Amgen employee heard that same doctor liken the Amgen rebates to "crack cocaine," and heard another doctor affiliated with Southeast Georgia state: "Amgen rebates keep my Porsche running." (160).

With respect to ICON, the FAC alleges that there was a "32-fold increase" in ICON's purchases of ESAs and Neupogen after ICON entered into an Amgen Portfolio Contract. Specifically, the FAC alleges that ICON spent \$1 million on Procrit and Neupogen in 2001, but \$32 million on Aranesp and Neupogen by 2006. (178). The FAC alleges that ICON had "no significant change in its patient population" during this period, in which cancer deaths were decreasing nationwide. (178).

Service of the Fifth Amended Complaint

On June 4, 2014, the Court issued summonses for the 18 Defendants named in the FAC. Relator claims that it served the summonses and copies of the FAC on

these defendants on or before July 2, 2014. *See* Proof of Service of Summons and Complaint upon All Defendants (Dkt. No. 97). One of the named defendants, Regional, failed to answer or move to dismiss the pleading.³ In one of its attempts to serve Regional, Relator's process server delivered a summons and a copy of the FAC to an employee of 21st Century, then the workplace of Alan R. Marks, M.D., the former President of Regional. 21st Century subsequently filed a motion to dismiss in which it argues, among other things, that it is not a party to this action. (21st Century's Memorandum of Law in Support of Motion to Dismiss, (Dkt. No. 149-10), p. 4). Because 21st Century is not now, and has never been, named a party to this action, its motion is moot and need not be discussed below.

The Motions to Dismiss

All Defendants other than Regional (collectively, the "Movants") now move to dismiss the FAC. Since some of the Movants are jointly represented, there are only ten motions to dismiss aside from 21st Century's motion. One of the most substantial of these was filed collectively by five of the Florida Defendants: FCS, New Hope, Coastal, Pasco Hernando and J. Paonessa, M.D., P.A., who was sued as GOA (collectively, the "FCS Defendants"). Similarly substantial are motions filed individually by USOS and Northwest Georgia, which make some of the same

³ In documents filed on November 20, 2014; December 9, 2014; and March 22, 2015, Relator requests that the Clerk of Court enter a default against Regional pursuant to Fed. R. Civ. P. 55(a) (Dkt. Nos. 161-62, 168). Because the Court is dismissing this action without prejudice, there is no need to address these requests.

arguments raised by the FCS Defendants. The motion filed jointly by GCS, Central Georgia, and Southeast Georgia (collectively, the “GCS Defendants”), the motion filed jointly by Treasure Coast and Mid-Florida and motions filed individually by Dresdner and by CIF largely join in the FCS Defendants’ motion. The motions filed individually by Augusta and Stuart do not expressly adopt the FCS Defendants’ Motion, but raise some of the same arguments contained therein. The motion filed individually by ICON joins in all other motions.

For ease of analysis, the Court groups the Movants’ arguments into five categories. First, the FCS Defendants argue that the Court lacks subject-matter jurisdiction because the essential elements of Relator’s claims were publicly disclosed prior to the filing of this action and because Relator was not an original source of the core information on which the *qui tam* action is based. The GCS Defendants, Northwest Georgia, Augusta, Dresdner, CIF, ICON, Treasure Coast and Mid-Florida join in this motion. USOS and Stuart do not join in this argument, but USOS asserts that this action is barred by the “first-to-file” rule because another relator was the first to file a lawsuit based on the facts alleged in the FAC. In support of that argument, USOS cites to another case which was filed in this district in 2004: *United States ex rel. Piacentile*, E.D.N.Y. Docket No. 04-CV-3983 (SJ). Northwest Georgia and CIF expressly join in this first-to-file argument.

Second, all of the motions argue that FAC violates Rule 9(b) of the Federal Rules of Civil Procedure in that it fails to plead the FCA claims with sufficient

particularity. Northwest Georgia argues, in the alternative, that the FAC violates Rule 8(a)'s "plausibility" requirement.

Third, all of the Movants seek to dismiss at least some of the FCA claims against them pursuant to Fed. R. Civ. P. 12(b)(6). The FCS Defendants argue that they did not violate the FCA by submitting claims to the Government which failed to report discounts or rebates that reduced the cost of the Amgen drugs for which those claims sought reimbursement. The FCS Defendants note that 42 C.F.R. § 1001.952(h)(1)(iii) provides that a buyer who does not report its costs on a "cost report" is not required to report discounts that are "made at the time of the sale of the good or service" or rebates that are "fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service." The FCS Defendant note that the FAC itself alleges that "[n]one of the defendant Oncology Practices qualified as a 'cost reporter,'" (143), and that the FAC's description of the "Amgen Portfolio Contracts" indicates that the discounts were made at the time of sale and that the rebates were fixed and disclosed in writing at the time of the initial sale. This same argument appears in the motions filed by Northwest Georgia, Augusta and Dresdner.

USOS makes a similar argument, albeit based on 42 C.F.R. § 1001.952(h)(2)—the subsection of § 1001.952(h) which applies to "sellers"—rather than § 1001.952(h)(1), which applies to "buyers." USOS argues that, as a "seller" to buyers who fit within § 1001.952(h)(1)(iii), it was only required to

inform the Government of rebates or discounts upon request by the Secretary of HHS or a State agency, and even then only if it was submitting a claim on behalf of the buyer for an item or service that is separately claimed. USOS notes that if the claims for reimbursement were filed by the buyer, it would only be required to “fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations” 42 C.F.R. § 1001.952(h)(2)(iii)(B).

USOS and Northwest Georgia both make the further argument that even if they failed to report discounts and rebates in making claims to the Government, their actions would not violate the FCA because they did not knowingly make false claims. These movants note that, to violate the FCA, a claimant must not only make a false claim but also know that it is false. Movants argue that even if their claims to the Government either certified or implicitly certified compliance with the Anti-kickback Statute, 42 U.S.C. § 1320a-7b, they believed that they were in compliance with the statute at the time the claims were filed. In addition, Northwest Georgia argues that an oncology practice’s failure to report rebates and discounts was immaterial to the Government’s payment decision, which was based on Amgen’s national sales data and not the price actually paid by the practice.

Some of the motions to dismiss also address the FCA's claims that Defendant's conspired with Amgen in violation of 31 U.S.C. §3729(a)(1)(C). The FCS Defendants note that Relator has not alleged facts to suggest that Amgen's customers knew anything about Amgen's unlawful practices, much less made an agreement to further those practices. Similarly, Northwest Georgia argues that the FAC alleges only that Amgen's purchasers benefitted from Amgen's manipulation of the AWP and ASP, but not that any of the purchasers knew that Amgen was engaged in that manipulation. USOS adds that the FAC does not allege an unlawful agreement among the medical providers, as is necessary to plead a "hub and spoke" conspiracy.

Fourth, the motions filed by FCS Defendants and Northwest Georgia argue that some of Relator's FCA claims may be time-barred. Both of these motions point out that the 31 U.S.C. § 3731(b) establishes a statute of limitations for civil actions brought pursuant under to 31 U.S.C. § 3730. However, the FCS Defendants and Northwest Georgia concede that they cannot argue that specific FCA claims are time-barred because 1) the FAC does not identify the allegedly false claims with particularity and 2) they do not know whether they were named as defendants in Relator's first two pleadings, which remained sealed at the time their motions were filed.

Fifth, most of the Movants argue that the State-law claims against them should be dismissed. The FCS Defendants and Stuart assert that the arguments for

dismissing the FCA claims also apply to the Florida False Claims Act since the latter is based on, and largely mirrors, the former. USOS makes a similar argument with respect to the 11 State-law claims asserted against it, and advances additional arguments with respect to the Georgia and Louisiana statutes. Northwest Georgia, Augusta and the GCS Defendants argue that Relator's claims pursuant to the Georgia False Medicaid Claims Act ("GFMCA") should be dismissed, noting that the statute was not effective until May 24, 2007—the day after Relator was terminated by Amgen.

Relator responds to all of these arguments in a single document entitled "Plaintiff's Consolidated Memorandum of Law in Response and Opposition to Defendants' Motions to Dismiss Complaint" ("Relator's Opposition"). Along with the memorandum, Relator has submitted a declaration in which he sets forth the allegations which he "could in good faith assert ... upon [his] own personal knowledge" as to each of the 18 Defendants. (Declaration of Don Hanks in Support of Relator's Opposition ("Hanks' Declaration")). Relator's Opposition and the Hanks Declaration are discussed below to the extent necessary to address Movants' arguments.

DISCUSSION

I. Restrictions on an FCA Claim

Before addressing the first category of arguments, which relates to two restrictions on FCA claims, the Court will briefly recap the salient provisions of the

FCA. The FCA currently provides that “any person who ... (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or] (C) conspires to commit a violation of subparagraph (A) [or] (B) ... is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 ..., plus 3 times the amount of damages which the Government sustains because of the act of that person.” 31 U.S.C.A. § 3729(a)(1). Civil actions for violations of the FCA may be brought by the U.S. Attorney General, who is charged with the responsibility of diligently investigating violations of § 3729. *See* 31 U.S.C. § 3730(a). In addition, the *qui tam* enforcement provisions of 31 U.S.C. § 3730(b) “allow a private party known as a ‘relator’ to bring an FCA action on behalf of the Government.” *State Farm Fire & Cas. Co. v. United States ex rel. Riggsby*, —U.S. —, 137 S. Ct. 436, 440 (2016).

When, as here, “a private person brings an action under § 3730(b), the Government may elect to ‘proceed with the action,’ § 3730(b)(4)(A), or it may ‘declin[e] to take over the action, in which case the person bringing the action shall have the right to conduct the action.’ § 3730(b)(4)(B).” *Rockwell Int’l Corp. v. United States*, 549 U.S. 457, 477 (2007). Regardless of which option the Government takes, the relator is generally entitled to an award in the form of a

Government takes, the relator is generally entitled to an award in the form of a percentage of the proceeds of the action or the settlement of the action. 31 U.S.C. § 3730(d). In cases where the Government does not proceed with the action, § 3730(d)(2) dictates that the relator's award "shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement."

"As originally enacted, the FCA did not limit the sources from which a relator could acquire the information to bring a *qui tam* action." *Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 293-94 (2010). However, the award provisions, which were intended to create "incentives for whistle-blowing insiders with genuinely valuable information," also encouraged suits by "opportunistic plaintiffs" with "no significant information to contribute of their own." *Id.* at 294. In an effort to discourage the latter, Congress amended the FCA to impose "a number of restrictions on suits by relators." *State Farm*, 137 S. Ct. at 440. Two of these restrictions—the "public disclosure bar" set forth in § 3730(e)(4) and the "first-to-file" rule set forth § 3730(b)(5)—have been raised by one or more of the Movants.

A. The Public Disclosure Bar

At the time this action was commenced in 2008, 31 U.S.C. § 3730(e)(4)(A) (1994) provided:

No court shall have jurisdiction over an action under [the FCA] based upon the public disclosure of allegations or transactions in a criminal, civil, or

administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

The term “original source” was defined in § 3730(e)(4)(B) as “an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.”

This “public disclosure bar” was amended as part of the Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (the “PPACA”), which was signed into law on March 23, 2010. This legislation replaced the prior version of 31 U.S.C. § 3730(e)(4)(A) with new language:

The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—

- (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
- (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
- (iii) from the news media,

unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

The amendment also modified the definition of “original source” to mean:

an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

31 U.S.C.A. § 3730(e)(4)(B).

As a preliminary matter, the Court must address the issue of which of these two versions of the public disclosure bar applies in this case. This issue is significant not only because the language of the two versions differs but because the 1994 version is jurisdictional, *Rockwell Int'l Corp.*, 549 U.S. at 467, while the 2010 version is not, *United States ex rel. Chorchos for Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 80 (2d Cir. 2017). Defects in subject-matter jurisdiction, which “involve[] a court’s power to hear a case, can never be forfeited or waived ... [and] require correction regardless of whether the error was raised in district court.” *United States v. Cotton*, 535 U.S. 625, 630 (2002). If a court “determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action” as to all defendants, including those defendants who chose not to raise the jurisdictional argument. Fed. R. Civ. P. 12(h)(3). In addition, the choice of which version of the statute applies dictates whether the § 3730(e)(4) arguments are analyzed pursuant to Rule 12(b)(1) or 12(b)(6).

The Supreme Court has repeatedly held that the 2010 amendments do not apply to cases that were pending as of March 23, 2010, when the PPACA was signed into law. *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 404, n.1 (2011); *Graham County*, 559 U.S. at 283, n. 1. Since this action has been pending since 2008, the 1994 version applies. Defendants' motions to dismiss this action pursuant to the public disclosure bar are analyzed under Rule 12(b)(1) of the Federal Rules of Civil Procedure.

"A Rule 12(b)(1) motion challenging subject matter jurisdiction may be either facial or fact-based." *Carter v. HealthPort Techs., LLC*, 822 F.3d 47, 56 (2d Cir. 2016). The former is "based solely on the allegations of the complaint or the complaint and exhibits attached to it (collectively the 'Pleading')." *Id.* In reviewing a facial attack to the court's jurisdiction, courts "draw all facts—which [are] ... assume[d] to be true unless contradicted by more specific allegations or documentary evidence—from the complaint and from the exhibits attached thereto." *Amidax Trading Grp. v. S.W.I.F.T. SCRL*, 671 F.3d 140, 145 (2d Cir. 2011). The plaintiff has no evidentiary burden with respect to these facial challenges. *Carter*, 822 F.3d at 56.

That is not true when a defendant makes "a fact-based Rule 12(b)(1) motion, proffering evidence beyond the Pleading." *Id.* at 57. "In opposition to such a motion, the plaintiffs ... need to come forward with evidence of their own to controvert that presented by the defendant 'if the affidavits submitted on a 12(b)(1)

motion ... reveal the existence of factual problems' in the assertion of jurisdiction.” *Id.* (quoting *Exchange National Bank of Chicago v. Touche Ross & Co.*, 544 F.2d 1126, 1131 (2d Cir. 1976)). “The plaintiff bears the burden of proving subject matter jurisdiction by a preponderance of the evidence.” *Mantena v. Johnson*, 809 F.3d 721, 727 (2d Cir. 2015) (quoting *Liranzo v. United States*, 690 F.3d 78, 84 (2d Cir. 2012)).

In this case, the FCS Defendants have made a fact-based Rule 12(b)(1) challenge to the Court’s subject-matter jurisdiction, arguing that the “essential elements” of Relator’s claims were publicly disclosed “in prior litigation, in the news media, and by the government itself.” Memorandum of Law in Support of Motion by the FCS Defendants (“FCS Memo”), p. 29. With the exception of USOS and Stuart, all of the Movants join in this argument, although none provide any additional cites or analysis in support of this point. In opposition to this argument, Relator contends that Defendants have not established that the FAC’s allegations have been previously publicly disclosed and, even if they have, that he is an “original source” of the information on which the allegations are based.

For the “public disclosure bar” to apply, “there must be ‘public disclosure’ of the information on which the allegation of fraud rests, and this ‘public disclosure’ must occur through one of the sources enumerated in the statute.” *United States ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94, 103 (2d Cir. 2010), *rev’d on other grounds*, 563 U.S. 401 (2011). In addition, “the public

disclosure (via an enumerated source) must be of the material elements of the ‘allegations or transactions’ on which the claim is based. 31 U.S.C. § 3730(e)(4)(A).” *Id.* As used in this subsection, the term “allegations” refers the relator’s allegations in the complaint as amended, not the allegations in the original pleading. *Rockwell Int’l Corp.*, 549 U.S. at 473. Accordingly, courts look to the most recent allegations in determining whether there is jurisdiction under § 3730(e)(4), even if those allegations are not contained in any pleading. *See, e.g., id.* at 474 (looking to the allegations in the pretrial order, since the pretrial order is deemed to amend any previous pleading).

Although the public disclosure must come “in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media,” these categories are construed broadly. *See Schindler Elevator Corp.*, 563 U.S. at 407-09. For example, the term, “report,” has its “broad ordinary meaning”: “‘something that gives information’ or a ‘notification,’ ... or ‘[a]n official or formal statement of facts or proceedings.’” *Schindler Elevator Corp.*, 563 U.S. at 407-08 (internal citations omitted). Similarly, the phrase “civil, criminal, or administrative hearing” includes “‘allegations and information disclosed in connection with civil, criminal, or administrative litigation,’ including information disclosed during discovery.” *United States ex rel. Smith v. Yale Univ.*, 415 F. Supp. 2d 58, 70 (D. Conn. 2006) (citing *United States ex rel. Stinson, Lyons, Gerlin & Bustamante*,

P.A. v. Prud. Ins. Co., 944 F.2d 1149, 1156 (3d Cir. 1991) & *United States ex rel. Siller v. Becton Dickinson & Co.*, 21 F.3d 1339, 1350 (4th Cir.1994)). A *qui tam* action does not have to be based *solely* upon allegations or transactions that have been publicly disclosed in an enumerated source in order for the public disclosure bar to apply. The word “‘solely’ ... is not included in § 3730(e)(4)(A).” *United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1158 (2d Cir. 1993). Accordingly, the Second Circuit has endorsed the view that § 3730(e)(4)(A) “applies to a ‘*qui tam*’ action ... based in any part upon publicly disclosed allegations or transactions.” *Id.* (quoting *United States ex rel. Precision Co. v. Koch Indus., Inc.*, 971 F.2d 548, 553 (10th Cir. 1992)).

There is disagreement in the Circuits as to the meaning of the phrase, “based upon,” as used in § 3730(e)(4)(A). “The majority view holds that as long as the relator’s allegations are substantially similar to information disclosed publicly, the relator’s claim is ‘based upon’ the public disclosure even if he actually obtained his information from a different source.” *United States ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 57 (1st Cir. 2009) (citing cases). The Fourth and Seventh Circuits “have interpreted the phrase more narrowly, requiring proof that the relator’s allegations are actually derived from the publicly disclosed information.” *Id.* (citing cases). The Second Circuit, which has held that “[p]ublic disclosure of the allegations divests district courts of jurisdiction over *qui tam* suits, regardless of where the relator obtained his information,” *United States ex rel. Doe*

v. John Doe Corp., 960 F.2d 318, 324 (2d Cir. 1992), adheres to the majority view. See *Ping Chen ex rel. U.S. v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 297 n. 11 (S.D.N.Y. 2013); *United States ex rel. Blundell v. Dialysis Clinic, Inc.*, No. 5:09-CV-00710 (NAM/DEP), 2011 WL 167246, at *6 (N.D.N.Y. Jan. 19, 2011).

As the FCS Defendants correctly note, this is the seventh of at least eleven *qui tam* actions to have been filed against Amgen and its customers in connection with Amgen's marketing practices. See FCS Memo, p. 1 n.1. The Court is very familiar with four of the six prior cases, since they either were, or are currently, before this Court: *United States ex rel. Cantor v. Amgen*, No. 04-CV-2511 (SJ)(RML); *United States ex rel. Piacentile v. Amgen*, No. 04-CV-3983 (SJ)(RML); *United States ex rel. Osiecki v. Amgen*, No. 05-CV-5025 (SJ)(RML); and *United States ex rel. Arriazola v. Amgen*, No. 06-CV-3232 (SJ)(RML). The other two prior cases—*United States ex rel. Westmoreland v. Amgen*, D. Mass. No. 06-CV-10972-WGY, and *United States ex rel. Horwitz v. Amgen*, W.D. Wash. No. C07-0248 BHS—are still pending in other districts.

The complaints in at least some of these prior actions alleged wrongdoing by Amgen and its customers which is nearly identical to some of the wrongdoing alleged in the FAC. However, none of the six prior cases were unsealed prior to the commencement of this action. The pleadings in all four of the cases that were, or are, pending before this Court remained sealed until December 20, 2012—more than four years after this action was commenced. The complaint in *United States*

ex rel. Westmoreland remained sealed until February 5, 2009—more than six months after the filing of original complaint in this action—and the pleading in *United States ex rel. Horwitz* has yet to be unsealed.

The FCS Defendants also cite to three non-*qui tam* cases which predated this action and which, they allege, involved substantially similar allegations. The first, *Citizens for Consumer Justice v. Abbott Laboratories, Inc.*, D. Mass. No. 01-CV-12257-PBS, was a class-action lawsuit filed in late 2001 by 13 non-profit organizations, alleging that pharmaceutical manufacturers, including Amgen, 1) overstated the AWP of various “Medicare Covered Drugs,” 2) promoted sales of the drugs by creating a “spread” between the costs of the drugs to healthcare providers and the amount of Medicare reimbursement and 3) encouraged the providers to claim Medicare reimbursement for free samples. The second, *County of Suffolk v. Abbott Laboratories, Inc.*, No. 03-CV-229 (DRH), alleged that dozens of pharmaceutical manufacturers, including Amgen, conspired with others, including physicians and other medical providers, in a fraudulent scheme “to collect inflated prescription drug payments” from the county-funded Medicaid program. The third case, *County of Westchester v. Abbott Laboratories, Inc.*, S.D.N.Y. No. 03-CV-6178 (SCR), resembled *County of Suffolk* in that it was brought by a county government against dozens of pharmaceutical manufacturers, including Amgen, alleging that the manufacturers artificially inflated and

fraudulent reported the AWP of their drugs, and failed to report “best prices,” as required by 42 U.S.C. § 1396r-8.

While none of these cases alleged a violation of the FCA, the Court finds that all three alleged fraudulent schemes which are substantially similar to Amgen’s practices in this case. In particular, *Citizens for Consumer Justice* specifically alleged the unlawful practices that are central to this case: inflating the AWP or other benchmarks on which the Government’s reimbursement for Covered Drugs is calculated, creating a “spread” between the reimbursement and the actual costs of the drugs, and encouraging GPOs, physicians and other healthcare providers to exploit that spread or other cost-reducing financial incentives to enrich themselves at the taxpayer’s expense.

Indeed, the Court notes that the FAC itself cites to *Citizens for Consumer Justice* as well as other cases in support of its allegations against Amgen. In paragraph 184, the FAC cites *In re Pharmaceutical Industry Average Wholesale Price Litigation*—the Multi-district Litigation which encompassed *Citizens for Consumer Justice*—in noting that Amgen and other drug manufacturers settled lawsuits in March 2008 which accused them of fraudulently inflating AWPs. In paragraph 180, the FAC cites to *Ortho Biotech Products, L.P. v. Amgen, Inc.*, D.N.J. Docket No. 2:05-CV-04580-SRC-MAS, in noting that Amgen settled a lawsuit in July 2008 accusing Amgen of tying the purchase of Aranesp to purchases of Neupogen and Neulasta.

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In addition, the FAC cites to several newspaper articles reporting on the effect Amgen's marketing practices had on patients and the public fisc. *See* FAC, ¶¶ 106-07, 216-17. One of these—an article entitled “Doctors Reap Millions for Anemia Drugs,” which appeared in *The New York Times* on May 9, 2007—is cited in paragraph 106 of the FAC to establish that United States physicians were overprescribing ESAs. The Court notes that the article—which is attached as Exhibit G to a declaration submitted in support of the FCS Memo (the “Kramer Declaration”)—also highlighted Amgen's use of rebates to promote the prescription of Aranesp and Epogen, implying that the practice led to overuse of the drugs. Although the article opined that Amgen's practices were “legal,” Kramer Declaration, Ex. G, p. 1, it implied that the practice had enriched physicians and noted that Medicare had “changed its payment structure since 2003” to account for the rebates. *Id.*, p. 2.

Based on the foregoing, the Court finds that this action is based in part upon allegations or transactions which were publicly disclosed in prior civil hearings and in the news media. However, since the public disclosure bar does not apply if the relator is an “original source,” the Court must address the question of whether Relator is an “original source” as defined in 31 U.S.C. § 3730(e)(4)(B).

B. Original Source

For the reasons set forth on page 34, *ante*, the Court must use the definition of “original source” set forth in the version of § 3730(e)(4)(B) that was in effect at

time this action was commenced in 2008. Under that definition, an “original source” is “an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.” As used in this definition, the term “information on which the allegations are based” refers to the information on which the relator’s allegations are based. *See Rockwell Int’l Corp.*, 549 U.S. at 470-71. With respect to the “relator’s allegations,” the Court “looks to the allegations as amended.” *Id.* at 474. Accordingly, “new allegations regarding a fundamentally different fraudulent scheme require reevaluation of the court’s jurisdiction.” *Id.* at 473.

The “original source” analysis is made on a claim-by-claim basis. “Section 3730(e)(4) does not permit jurisdiction in gross just because a relator is an original source with respect to some claim.” *Id.* at 476. As then-Judge Alito explained in *United States ex rel. Merena v. SmithKline Beecham Corp.*, 205 F.3d 97 (3d Cir. 2000):

The plaintiff’s decision to join all of his or her claims in a single lawsuit should not rescue claims that would have been doomed by section (e)(4) if they had been asserted in a separate action. And likewise, this joinder should not result in the dismissal of claims that would have otherwise survived.”

Id. at 102.

In this case, the FAC alleges a single federal claim, which alleges violations of the FCA. Relator is not actually alleging a single false claim, but multiple false

claims arising from a common scheme. Presumably, Relator is alleging that each Defendant made, or caused to be made, a series of false claims to Government Healthcare Programs for reimbursement for Covered Drugs. In addition, paragraph 232 of the FAC suggests that the FCA claim encompasses several different theories of liability.

Relator appears to an original source with respect to at least some claims. For example, allegations in the FAC suggest that Relator has direct and independent knowledge of circumstantial evidence that Southeast Georgia and ICON were prescribing Aranesp and Neupogen to patients for whom the drugs were not medically necessary. *See* FAC ¶¶ 173, 178, 215. In addition, the Hanks Declaration alleges that he had conversations with Southeast Georgia and ICON employees who tacitly admitted that their entity's rapidly increasing use of Aranesp could not be medically justified. *See* Hanks Declaration, ¶¶ 6A & 20B.

Conversely, it is clear that Relator is not an original source with respect to claims that were filed after mid-2007. While the FAC purports to seek damages for FCA violations that occurred during the period from September 1, 2001, to at least September 30, 2011 (FAC ¶ 2), Relator was terminated by Amgen on May 23, 2007. (FAC ¶ 20). Accordingly, the FAC does not allege sales figures with respect to any Defendant for years after 2007. Indeed, for 14 of the 18 Defendants, the FAC only alleges the dollar amount of drugs purchased by that defendant during the Fourth Quarter of 2006 and speculates, upon information and belief, that these

defendants “made comparable purchases of Amgen drugs and received comparable rebates” on those purchases for the entire period from September 1, 2001, to at least September 30, 2011. (39-62).

As discussed in Section II, *post*, the FAC does not plead Relator’s federal and state FCA claims with sufficient particularity. Accordingly, the Court cannot adjudicate the jurisdictional argument at this juncture. The Court cannot find that Relator has subject-matter jurisdiction with respect to all of the federal FCA claims conceivably encapsulated within paragraph 232 of the FAC. *See Rockwell Int’l Corp.*, 549 U.S. at 476. Yet, because the FAC lumps all of the FCA claims together in a single cause of action, the Court cannot dismiss that cause of action without dismissing claims over which this Court has jurisdiction. Therefore, the Court will deny the motion to dismiss pursuant to § 3730(e)(4) at this juncture.

C. First-to-File Bar

USOS, Northwest Georgia and CIF (by expressly joining in Point I of USOS’s brief) argue that this action is barred by the “first-to-file” rule, set forth in 31 U.S.C. § 3730(b)(5). Unlike the public disclosure bar, the first-to-file bar was not amended by the PPACA. At all times since the inception of this case, § 3730(b)(5) has provided: “When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.”

The Memorandum of Law in Support of USOS's Motion to Dismiss (the "USOS Memo"), which is dated August 1, 2014, assumes that the first-to-file bar is jurisdictional and that this argument should be analyzed under Fed. R. Civ. P. 12(b)(1). See USOS Memo, p. 7. Several circuits have also made this assumption. See, e.g., *United States ex rel. Carter v. Halliburton Co.*, 710 F.3d 171, 181 (4th Cir. 2013), *aff'd in part, rev'd in part on other grounds sub nom. Kellogg Brown & Root Servs., Inc. v. U.S., ex rel. Carter*, —U.S.—, —, 135 S. Ct. 1970 (2015)); *United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 376-77 (5th Cir. 2009); *Walburn v. Lockheed Martin Corp.*, 431 F.3d 966, 970 (6th Cir. 2005). In April 2017, however, the Second Circuit expressly rejected this view, joining the D.C. Circuit in "holding that the first-to-file rule is not jurisdictional and instead bears on the merits of whether a plaintiff has stated a claim." *United States ex rel. Hayes v. Allstate Ins. Co.*, 853 F.3d 80, 85 (2d Cir.), *cert. denied*, 138 S. Ct. 199 (2017).

This first-to-file argument, therefore, must be analyzed under Fed. R. Civ. P. 12(b)(6) and not 12(b)(1). See *United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 168 (2d Cir. 2018) (analyzing a first-to-file issue under Rule 12(b)(6)). In considering a motion to dismiss pursuant to Rule 12(b)(6), a court must accept all factual allegations in the complaint as true, and draw all reasonable inferences in the plaintiff's favor. See *Rothstein v. UBS AG*, 708 F.3d 82, 90 (2d Cir. 2013). However, "the tenet that a court must accept as true all of the allegations contained

in a complaint is inapplicable to legal conclusions,” and “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice” to state a claim. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). To survive a motion to dismiss, a complaint must allege “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). If a party has not “nudged [her] claims across the line from conceivable to plausible, the[] complaint must be dismissed.” *Id.*

“Because a Rule 12(b)(6) motion challenges the complaint as presented by the plaintiff, taking no account of its basis in evidence, a court adjudicating such a motion may review only a narrow universe of materials.” *Goel v. Bunge, Ltd.*, 820 F.3d 554, 559 (2d Cir. 2016). Generally, courts “do not look beyond ‘facts stated on the face of the complaint, ... documents appended to the complaint or incorporated in the complaint by reference, and ... matters of which judicial notice may be taken.’” *Id.* (quoting *Concord Assocs., L.P. v. Entm’t Props. Tr.*, 817 F.3d 46, 51 n. 2 (2d Cir. 2016)). “A court may take judicial notice of a document filed in another court not for the truth of the matters asserted in the other litigation but rather to establish the fact of such litigation and related filings.” *Global Network Commc’ns, Inc. v. City of New York*, 458 F.3d 150, 157 (2d Cir. 2006).

In analyzing the first-to-file argument in this case, it is important to bear in mind that “a claim is barred by the first-to-file bar if at the time the lawsuit was brought a related action was pending.” *United States ex rel. Wood*, 899 F.3d at 172

(emphasis in original). For purposes of § 3730(b)(5), the phrase, “brings an action,” and the term, “pending,” have their ordinary meaning. “To ‘bring an action’ is to ‘institute legal proceedings.’” *Id.* (quoting *Black’s Law Dictionary* 231 (10th ed. 2014)). “The term ‘pending’ means ‘[r]emaining undecided; awaiting decision.’” *Kellogg Brown & Root Servs.*, 135 S. Ct. at 1978 (quoting *Black’s Law Dictionary* 1314 (10th ed. 2014)). As for the term, “related,” the Second Circuit recently stated:

“A second action is ‘related,’ within the meaning of [Section 3730(b)(5),] if the claims incorporate ‘the same material elements of fraud’ as the earlier action, even if the allegations incorporate additional or somewhat different facts or information.” *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 121 (D.C. Cir. 2015) (quoting *United States ex rel. Hampton v. Columbia/HCA Healthcare Corp.*, 318 F.3d 214, 217 (D.C. Cir. 2003)). In other words, to be related, the cases must rely on the same “essential facts.” *United States ex rel. Wilson v. Bristol-Myers Squibb, Inc.*, 750 F.3d 111, 117 (1st Cir. 2014) (collecting cases). If the first-filed complaint ensures that the Government “would be equipped to investigate” the fraud alleged in the later-filed complaint, then the two cases are related within the meaning of Section 3730(b)(5). *Heath*, 791 F.3d at 121.

United States ex rel. Wood, 899 F.3d at 169 (brackets in original).

“[A] first-to-file violation cannot be cured by amending or supplementing a complaint, even when the first-filed case is no longer pending.” *Id.* at 175.

“[A]mending or supplementing a complaint does not *bring* a new action, it only *brings* a new complaint into an action that is already pending.” *Id.* at 172.

(emphasis in original). Moreover, actions filed in violation of the first-to-file rule cannot simply be stayed “indefinitely awaiting the potential dismissal of the first-filed action.” *Id.* at 173. Rather, they must be dismissed without prejudice. *Id.*

In arguing that this action is barred by the first-to-file rule, USOS and Northwest Georgia both rely on *United States ex rel. Piacentile v. Amgen, supra*—a case which was filed with this Court in September 2004. The Amended Complaint in *Piacentile*—which was the operative pleading at the time this action was filed—alleged wrongdoing by Amgen and one of its customers which is nearly identical to the wrongdoing alleged in Relator’s initial complaint in this case. Relator’s Opposition does not question that *Piacentile* is based on the same essential facts as this action or that it was filed before this case. Rather, Relator argues 1) that *Piacentile* was dismissed during the pendency of this action, 2) that *Piacentile* “charged only one of the current Defendants ... with violating the FCA” in the manner alleged in the FAC and 3) that “important policy considerations ... favor allowing a filer who may have brought an action subsequent to, but without knowledge of, an earlier filed motion” to proceed with his or her case. Relator’s Opposition, pp. 36-37. None of these arguments have any merit.

Relator’s first argument is meritless for two reasons. First, as emphasized above, a *qui tam* action is barred by the first-to-file rule if, at the time it is filed, a related action is already pending. See *United States ex rel. Wood*, 899 F.3d at 172. Since the first-to-file rule bars prohibits the *bringing* of an action, any subsequently

filed, related action must be dismissed even if the first-filed action is dismissed while the second action is still pending. *See id.*

Second, *Piacentile* has not been dismissed. Relator relies on *United States ex rel. Piacentile v. Amgen Inc.*, No. 04-CV-3983 (SJ)(RML), 2013 WL 5460640 (E.D.N.Y. Sept. 30, 2013), which errantly directed the Clerk of Court to close *Piacentile*, *id.* at *4, and prompted the Clerk of Court to enter a judgment. *See Piacentile* Dkt. No. 122. However, that memorandum and order only granted the United States' motion to dismiss its claims against Amgen. It did not dismiss the claims against the other five defendants named in *Piacentile*'s Third Amended Complaint. Indeed, in its Notice of Declination in Part, in which the United States declined to intervene in the claims against those defendants, the Government expressly noted that the relators had the right, under 31 U.S.C. § 3730(b)(1), to "maintain the declined portion of the action in the name of the United States." Notice of Declination in Part dated Dec. 19, 2012 (*Piacentile* Dkt. No. 56), ¶ 3.

The judgment that was entered pursuant to the memorandum and order was ambiguous, stating that it was "adjudged that the government's motion to dismiss is granted; and that the Relators' motion to amend the Third Amended Complaint is denied as futile." On appeal from that judgment, the Second Circuit addressed that ambiguity by directing the Court to "clarify whether it intended to grant judgment on the entire case ... or only on the claims against Amgen." Mandate issued Mar. 11, 2014 (*Piacentile* Dkt. No. 123). While the Court has yet to formally vacate the

judgment, the Court's actions at a March 28, 2014, status conference made it clear that *Piacentile* remains pending.

The second argument raised by Relator evinces a misunderstanding of the first-to-file rule. As explained above, the first-to file rule “prevents an individual from bringing an FCA *qui tam* action if another action invoking the same facts is already pending at the time the individual files suit.” *United States ex rel. Hayes*, 853 F.3d at 85 (citing *Kellogg Brown & Root Servs.*, 135 S. Ct. at 1974, 1978). Since the determination of relatedness is made as of time the later-filed action is brought, the plaintiff filing that action cannot avoid application of the first-to-file rule through subsequent amendments to the pleading. See *United States ex rel. Wood*, 2018 WL 3763731 at *9. Accordingly, the fact that “only one of the *current* Defendants” is named in both *Piacentile* and the FAC is irrelevant to the first-to-file analysis.

To determine relatedness, the Court compares Relator's original pleading to the pleadings in actions that were pending at the time this action was commenced. Relator's original complaint alleged that Amgen had defrauded government healthcare programs by “falsely representing the prices of its drugs, engaging in improper sales and marketing schemes such as promoting off-label sales and ‘marketing the spread,’ and paying illegal kickbacks to physicians.” Original Complaint (Dkt. No. 10), ¶ 2. The pleading further alleged that three Amgen customers—FCS, GOA and ICON—received kickbacks from Amgen, which they

failed to disclose in submitting claims for reimbursement to government healthcare programs. *Id.*, ¶¶ 28-32.

Although the Amended Complaint in *Piacentile* named only Amgen and U.S. Oncology, that pleading and the FAC “rely on the same essential facts.” *See United States ex rel. Wood*, 899 F.3d at 169 (internal quotations and citations omitted). The Amended Complaint in *Piacentile* alleged that Amgen paid “kickbacks” to physicians in order to induce them to prescribe the Drugs, “marketed the spread,” and engaged in a clandestine off-label marketing scheme. It further alleged that an Amgen customer, U.S. Oncology, then filed claims for reimbursement with government healthcare programs which failed to disclose the kickbacks and other unlawful remuneration it received from Amgen. While the Amgen customers named in *Piacentile* and this action differ, it is beyond dispute that the two actions incorporated “the same material elements of fraud,” even if they incorporated “somewhat different facts or information.” *See United States ex rel. Wood*, 899 F.3d at 169.

Relator’s third argument is not only unsupported by any authority but, as explained by the Second Circuit in *United States ex rel. Wood v. Allergan, Inc.*, *supra*, is contrary to the FCA’s statutory language. In *United States ex rel. Wood*, as here, the relator filed his action at a time when prior actions alleging similar FCA violations were pending but still under seal. All of the prior actions were dismissed on procedural grounds before the defendant, Allergan, moved to dismiss

the action on first-to-file grounds. Although dismissal, even without prejudice, created a possibility that the relator's claims would be time-barred and that Allergan would escape FCA liability, the Second Circuit held that the plain language of § 3730(b)(5) required this result, stating: "The statutory command is not ambiguous: a claim is barred by the first-to-file bar if at the time the lawsuit was brought a related action was pending." *United States ex rel. Wood*, 899 F.3d at 172. In so ruling, the Second Circuit acknowledged:

The FCA's scheme is difficult for relators, who may substantially invest in claims, only to find out that a recently unsealed complaint blocks their action, months if not years down the road. This, however, is how Congress designed the statutory scheme, and it is carefully calibrated to strike "the golden mean between adequate incentives for whistle-blowing insiders ... and discouragement of opportunistic plaintiffs." [*United States ex rel. Springfield Terminal Ry. Co. [v. Quinn]*, 14 F.3d [645,] ... 649 [(D.C. Cir. 1994)]].

Id. at 174.

In keeping with *United States ex rel. Wood*, *supra*, this action must be dismissed without prejudice pursuant to § 3730(b)(5). Relator may re-file this action after all prior-filed, related actions are dismissed.

II. Rules 8(a) and 9(b)

Since there is some possibility that this action will be re-filed, the Court will briefly address Defendants' claims pursuant to Rule 8(a) and 9(b) of the Federal

Rules of Civil Procedure.⁴ Generally, a pleading need only contain “(1) a short and plain statement of the grounds for the court’s jurisdiction ... ; (2) a short and plain statement of the claim showing that the pleader is entitled to relief; and (3) a demand for the relief sought” Fed. R. Civ. P. 8(a). However, when “alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). Even when Rule 9(b) applies, “Malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” *Id.*

Since it is “self-evident that the FCA is an anti-fraud statute[,] ... courts routinely require FCA claims to comply with Rule 9(b).” *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476-77 (2d Cir. 1995). In this case, all 17 Defendants who filed or joined in a motion to dismiss argue that the FAC violates Rule 9(b) of the Federal Rules of Civil Procedure by failing to allege the FCA claim with sufficient particularity. Northwest Georgia also argues, in the alternative, that “the FAC comes nowhere close to satisfying Rule 8.” Memorandum of Law in Support of Northwest Georgia’s Motion to Dismiss (“Northwest Georgia Memo”), p. 8. The Court finds that the FAC fails meet the more exacting Rule 9 standard, which

⁴ The Court recognizes that Relator may be barred from re-filing by the statute of limitations. The statute of limitations for FCA claims is generally six years, *see* 31 U.S.C. § 3731(b), and the Covered Period ended on September 30, 2011. However, the risk that possibly meritorious claims will never be prosecuted “is always present when there is a statute of limitations, and it is weighed against countervailing concerns of Congress.” *United States ex rel. Wood*, 899 F.3d at 174.

applies to both Relator's federal and state claims, and does not reach Northwest Georgia's argument.

Ordinarily, Rule 9(b) "requires a complaint alleging fraud to (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *United States ex rel. Chorches*, 865 F.3d at 81 (quoting *United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 25 (2d Cir. 2016)). "The purpose of Rule 9(b) is threefold—it is designed to provide a defendant with fair notice of a plaintiff's claim, to safeguard a defendant's reputation from improvident charges of wrongdoing, and to protect a defendant against the institution of a strike suit." *United States ex rel. Ladas*, 824 F.3d at 25 (quoting *O'Brien v. National Property Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991)). The Second Circuit recognizes and rigorously enforces "these salutary purposes of Rule 9(b)." *Id.* (quoting *Ross v. Bolton*, 904 F.2d 819, 823 (2d Cir. 1990)).

"Despite the generally rigid requirement [of Rule 9(b)], allegations may be based on information and belief when facts are peculiarly within the opposing party's knowledge." *United States ex rel. Chorches*, 865 F.3d at 81-82 (quoting *Wexner v. First Manhattan Co.*, 902 F.2d 169, 172 (2d Cir. 1990)). Still, a plaintiff alleging fraud on information and belief must have "sufficient data to justify interposing an allegation on the subject" and the complaint must "adduce specific facts supporting a strong inference of fraud." *Id.* at 82 (internal quotations and

citations omitted). *Wexner*, 902 F.2d at 172. Similarly, “while Rule 9(b) permits scienter to be demonstrated by inference, this ‘must not be mistaken for license to base claims of fraud on speculation and conclusory allegations.’” *O’Brien*, 936 F.2d at 676 (quoting *Wexner*, 902 F.2d at 172).

Even assuming that some facts relating to the claims for reimbursement are peculiarly within the knowledge of the Defendants, the FAC fails to allege any of the FCA or state-law claims with sufficient particularity. First, the FAC broadly alleges that each of the 18 Defendants filed unspecified claims with one or more of the seven federal health care programs listed in paragraphs 218-228 of the FAC. The pleading does not allege what, if any, form was used to file the claims, or whether the forms used contain any express or implied certifications.

Second, while the FAC alleges that the FCA violations “occurred during the period [from] September 1, 2001 to at least September 30, 2011,” FAC ¶ 2, the pleading does not alert the individual Defendant to when during that decade-long period the claims at issue were filed or how many false claims each Defendant allegedly filed. The dates (or range of dates) on which each Defendant made a claim or claims are not only necessary to determine the timeliness of Relator’s claims, but also necessary to permit Defendants to determine which version of the law applies to the various claims. Both the FCA and the Anti-kickback Statute were amended in 2010 in ways that may determine the viability of some of Defendants’ claims.

Third, the FAC does not adequately explain Relator's theory or theories of liability. Some Defendants have construed the pleading as alleging that Defendants submitted false claims by failing to report the discounts, rebates and other financial benefits they received from Amgen. The Court, in contrast, interprets the FCA claim as alleging a false implied certification claim, asserting that the claims which Defendants filed with government healthcare programs implicitly and falsely certified compliance with the Anti-kickback Statute. Similarly, the Court perceives the FAC as alleging that at least some the Defendants violated the FCA by overprescribing drugs or prescribing drugs unnecessarily. None of the motions to dismiss addressed this argument, even though there are no allegations suggesting that any of the Defendants, with the possible exception of Southeast Georgia and ICON, engaged in this unethical behavior.

CONCLUSION

For the reasons stated above, Defendants' motions are denied to the extent that they argue that this Court lacks subject-matter over this action by virtue of the public disclosure bar set forth in 31 U.S.C. § 3730(e)(4)(A) (1994). Defendants' motions are granted, however, to the extent that Defendants argue that this action must be dismissed without prejudice for violation of the first-to-file rule, 31 U.S.C. § 3730(b)(5) and Rule 9(b)'s requirement that claims under the False Claims Act and analogous state statutes be pled with particularity. This action is dismissed without prejudice to refiling this action after all prior-filed, related actions are

dismissed. The Clerk of Court is directed to enter judgment in accordance with this Memorandum and Order and to close this case.

SO ORDERED.

Dated: September 12, 2018
Brooklyn, New York

/s/(SJ)

Sterling Johnson, Jr., U.S.D.J.